REMARKS

Entry of this amendment and reconsideration of this application, as amended, are respectfully requested.

It is believed that the §112, second paragraph rejections of the claims are rendered moot by the amendments to the claims.

Claims 29-31 were rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirements. Applicant respectfully traverses, but has, nonetheless, deleted the term "directly" from appropriate claims. As the Examiner notes, page 2, lines 27-37 to page 3, lines 1-6 of the specification provide support for plant, animal and unicellular organism sources.

The 35 U.S.C. §112, first paragraph rejection of claims 15, 19, 20 and 21-37 for allegedly failing to comply with the written description requirement for being drawn to a "broad genus" of methods of treatment is respectfully traversed.

The claimed invention is directed to the use of xenogeneic oligo-and/or polyribonucleotides to treat Herpesviridae infection or skin tumors. The examples provide methods of obtaining the active agent from, e.g., yeast, provide analysis results of the resultant product, and *in vivo* experiments, including the results of a double blind study. In view of the foregoing, it is submitted that there is sufficient written description of the claims.

With regard to the §102(b) rejection based on Draper, the Examiner alleges that Draper discloses a method of treating a virus caused disease by administering an enzymatic RNA molecule. Draper uses an enzymatic RNA molecule which is capable of specifically cleaving RNA of particular viruses, or is encoded thereby. Draper's enzymatic RNA molecules, also referred to as ribozymes, as clearly stated on page 76, line 25 et seq., are either prepared by genetic engineering methods or chemically synthesized. Thus, they are not naturally occurring

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ribozymes. There is no hint or suggestion that Draper's ribozymes might occur naturally. Rather, Draper is concerned with ribozymes which are prepared by complicated methods and are active against quite specific sites of the virus genome. Draper does not teach or suggest to use natural RNAs from animals, plants and unicellular organisms. In particular, the description of the production of suitable ribozymes starting on page 76, line 25 makes it clear that artificial substances produced by complicated synthesis are concerned.

Also note that none of the cited references disclose how the recurrences typically found in the case of herpes infections (i.e., the renewed occurrence of the symptoms after they had already disappeared) can be avoided. It is important to note that the active agent is applied only one single time per occurrence of the disease, i.e., not several times until all symptoms have disappeared.

Claims 15 and 20, 21, 23, 27, 29, 31-32 and 36 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Dirheimer. Applicant respectfully traverses. Dirheimer discloses a tRNA preparation which also contains DNA and applicable as an antiviral agent. The agent is used in aqueous medium above all and must be applied daily or every other day. The possibility of avoiding recurrence is not disclosed; the claimed invention, however, prevents recurrences and must be used in water-free medium and need not be administered daily or even every other day, but may be administered only once per recurrence.

As evidence of patentability, the allowed claims of corresponding EP 1,206,267 are attached.

In view of the foregoing, allowance is respectfully requested.

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If any fees are due to enter this amendment or to maintain pendency of this application, please charge the fees to Deposit Account No. 50-0624.

Respectfully submitted

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(54) **ARZNEIMITTEL ENTHALTEND XENOGENE OLIGO- ODER/UND POLYRIBONUKLEOTIDE**

MEDICAMENTS CONTAINING XENOGENIC OLIGO- OR/AND POLYRIBONUCLEOTIDES

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Anmerkung: Innerhalb von neun Monaten nach der Bekanntmachung des Hinweises auf die Erteilung des europäischen Patents kann jedermann beim Europäischen Patentamt gegen das erteilte europäische Patent Einspruch einlegen. Der Einspruch ist schriftlich einzureichen und zu begründen. Er gilt erst als eingelegt, wenn die Einspruchsgebühr entrichtet worden ist. (Art. 99(1) Europäisches Patentübereinkommen).

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Claims

1. Use of xenogeneic oligo- and/or polyribonucleotides for producing an anhydrous medicament for the topical treatment of infections by Herpesviridae and/or skin tumours, the medicament being applied once per recurrence.

2. Use according to Claim 1, **characterized in that** the medicament additionally comprises physiologically acceptable carriers, excipients, diluents and/or additives.

3. Use according to Claim 1 or 2, **characterized in that** the xenogeneic oligo- and/or polyribonucleotides originate from organisms which are evolutionarily distant from the organism to be treated.

4. Use according to any of the preceding claims for the treatment of lesions of the skin and/or mucosa, caused by herpes simplex virus and/or varicella zoster virus.

5. Use of xenogeneic oligo- and/or polyribonucleotides for producing an anhydrous medicament for the treatment of infections by Herpesviridae and/or skin tumours by administering an active amount of 0.1 mg and higher per dose unit once per recurrence.

Revendications

1. Utilisation d'oligoribonucléotides et/ou polyribonucléotides xénogènes pour la fabrication d'un médicament anhydre pour le traitement topique d'infections herpétiques et/ou de tumeurs cutanées, où le médicament est utilisé en application unique à chaque récidive.

2. Utilisation selon la revendication 1, **caractérisée en ce que** le médicament contient également des excipients, des adjuvants, des diluants et/ou des additifs physiologiquement acceptables.

3. Utilisation selon la revendication 1 ou 2, **caractérisée en ce que** les oligoribonucléotides et/ou polyribonucléotides xénogènes proviennent d'organismes phylogénétiquement éloignés de l'organisme à traiter.

4. Utilisation selon l'une des revendications précédentes dans le traitement des lésions de la peau et/ou des muqueuses dues au virus herpès simplex (HSV) ou au virus zona-varicelle (VZV).

5. Utilisation des oligoribonucléotides et/ou polyribonucléotides pour la production d'un médicament anhydre dans le traitement des infections herpétiques et /ou des tumeurs cutanées via l'administration en quantité efficace de 0,1 mg en prise unique à chaque récidive.

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